

I. 35 U.S.C. 102(b) Rejection

Reconsideration is requested of the rejection of claims 1-5, 35, 37, 78-79, 81 and 85-93 under 35 U.S.C. 102(b) in view of European Patent Publication No. 0248215 B1 ("EP 215").

A. **Summary of Rejected Claims**

Claims 1 and 3 are generally directed toward a method for the selective inhibition of cyclooxygenase-2 (COX-2) activity in an organism by administering to the organism an organic extract of the edible plant of the genus *Vitex* and of the species *agnus-castus*.¹ Claim 2 depends from claim 1 and further requires that the inhibitory effect of the organic extract on COX-2 is 2 times greater than its inhibitory effect on cyclooxygenase-1 ("COX-1"), and claims 4 and 5 depend from claim 3 and further require that the inhibitory effect of the organic extract on COX-2 is 2 times greater than its inhibitory effect on cyclooxygenase-1 ("COX-1") or 10 times greater than its inhibitory effect on COX-1, respectively.² Moreover, claims 78, 79 and 81 depend from claim 1 and further recite details pertaining to the organic extraction process. Claim 85 is directed toward a method to prevent COX-2 mediated inflammation by the administration of the extract purified in claim 78 (which depends from claim 1). Additionally, claims 86-93 depend from claim 85 and further recite specific disease states that are benefitted by the method of claim 85.

¹ Claim 1 is directed toward selective inhibition of COX-2 via administration of an organic extract of an edible plant. Due to the election of species requirement, however, only extracts from the genus *Vitex* and of the species *agnus-castus* are presently under consideration.

² Claim 35 depends from claim 3 and requires the extract be isolated from a plant of the Lamiales order selected from the families Lamiaceae and Verbenaceae. Claim 37 depends from claim 35 and further requires that the extract is from the genus *Vitex*.

B. The Office Has Not Provided Rationale or Evidence Tending to Show Inherency

The Office has rejected claims 1-5, 35, 37, 78-79, 81, and 85-93 under 35 U.S.C. 102(b) based upon the theory of inherency. In support of its rejection, the Office asserts that "EP [EP 215] teaches an alcohol extract of *Vitex agnus-castus*...The extract when administered to a patient will inherently produce the claimed results." This assertion has no foundation.

To properly support a determination of inherency, as a matter of Patent Office practice, it is incumbent on the Examiner to first provide rationale or evidence tending to show inherency.³ In establishing this rationale or evidence, the Examiner must provide a basis in fact and/or technical reasoning to support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the cited art.⁴ Furthermore, the mere fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that characteristic.⁵ Only after this initial burden of proof has been met by the Office, does the burden shift to the Applicant.

Against the backdrop of this legal standard, the Office has not properly supported its determination of inherency. To date, as the sole basis for its rejection, the Office has merely stated that the "...extract when administered to a patient will inherently produce the claimed results." No rationale or evidence has been provided by the Office to support this conclusion. Moreover, no facts or technical reasoning are

³ See MPEP § 2112.

⁴ Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

⁵ 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

provided by the Office to support a determination that the allegedly inherent characteristic necessarily flows from the disclosure of the cited art. For example, why will the composition disclosed in EP 215 selectively inhibit COX-2 when administered to an organism in the same manner as the compositions employed in the methods of the instant invention? Contrary to both the law and Office policy, accordingly, the Office simply has not articulated a proper basis for this rejection.

C. Applicants Have Discovered a New Use For Vitex agnus-castus Organic Extracts

Claims 1-5, 35, 37, 78-79, 81, and 85-93, are novel in view of the cited art because EP 215 does not disclose each and every element of the invention as claimed. These claims, as stated above, are all generally directed toward a **method** for the **selective inhibition of cyclooxygenase-2** (COX-2) activity in an organism by administering to the organism an organic extract of *Vitex agnus-castus*. EP 215, on the other hand, discloses an alcohol extract of ***Vitex* fruits** employed to treat diseases caused or influenced by **dopamine deficiency**. Nowhere in EP 215 is it disclosed or even suggested that its composition has the ability to selectively inhibit Cox-2, or even inhibit Cox-2, for that matter. Moreover, nowhere is it disclosed or suggested that this composition could even be employed for the treatment of inflammation or inflammation related diseases.

Even assuming, *arguendo*, that the composition of EP 215 and the organic extract composition of the instant invention are the same, EP 215 does not destroy the novelty of the instant invention based upon the theory of inherency. It is well established that a new and unobvious use of a known composition

is patentable to the discoverer as a process of using.⁶ In this case, as stated above, Applicants have discovered a new use, selective inhibition of COX-2, for a composition asserted to be known, extracts of *Vitex* fruits. Nowhere does EP 215 disclose or even suggest this use. Based upon this new use, method claims 1-5, 35, 37, 78-79, 81, and 85-93 are novel in view of EP 215.

In view of the foregoing argument, Applicants respectfully traverse this basis for rejection of claims 1-5, 35, 37, 78-79, 81, and 85-93 and request its reconsideration and withdrawal.

II. 35 U.S.C. 103(a) Rejection

Reconsideration is requested of the rejection of claims 1-5, 35, 37, 78-79, 81, and 85-93 under 35 U.S.C. 103(a) in view of EP 215, Hawley's Condensed Chemical Dictionary ("Hawley's"), and additionally in combination with Japanese Patent Publication Number 2000236835 ("JP 835").

Claims 1-5, 35, 37, 78-79, 81, and 85-93 are not obvious in view of the cited art, either alone or in combination. In support of its rejection, however, the Office states that EP 215 discloses that *Vitex agnus-castus* alcohol extracts can be used to treat diseases caused by dopamine deficiency, that Hawley's discloses the use of methylene chloride as a solvent for extraction, and that JP 835 discloses that an extract from *Vitex agnus-castus* is used in food for the prevention of cancer. Accordingly, the Office asserts that the skilled artisan would reasonably expect that the EP 215 composition could be extracted from *Vitex agnus-castus* with the organic solvent disclosed in Hawley's and that this extract would also be expected to inhibit Cox-2 based upon the combined disclosure of EP 215 and JP 835. These assertions are not supported by the cited art.

⁶ See MPEP 2112.02 and *In re Hack*, 114 USPQ 161, 163 (CCPA 1957).

The Office, as with its 102(b) rejection, appears to be relying on the theory of inherency for its 103(a) rejection. If so, the Office has not established a *prima facie* case of inherency. The law requires more than an unsupported statement by the Office that the "...extract [disclosed in EP 215] when administered to a patient will inherently produce the claimed results." No facts or technical reasoning have been provided by the Office to support a determination that the allegedly inherent characteristic necessarily flows from the teaching of the cited art, as required by law. Without this demonstration, the Office has not met its burden of proof as required by law.

Moreover, the Office's reliance on inherency is also misplaced in view of express limitations recited in claims 1-5, 35, 37, 78-79, 81, and 85-93. These claims are all generally directed toward a **method** for the selective inhibition of COX-2 or for the treatment of Cox-2 mediated conditions by administering an organic extract of *Vitex agnus-castus*. It is well established that a new and unobvious use of a known composition is patentable to the discoverer as a process of using.⁷ In this case, as stated above, Applicants have discovered a new use, selective inhibition of COX-2, for a known composition, *Vitex agnus-castus* extracts. Nowhere does the cited art, either alone or in combination, disclose or even suggest this use.

Moreover, based upon the collective disclosures of EP 215 and JP 835, this use is not obvious. As stated above, the suggested use for the composition disclosed in EP 215 is for the treatment of **dopamine deficiency**. Dopamine deficiency, as is well known in the art, has been implicated as a causative factor in many **neurological diseases or disorders**, such as Attention Deficit Disorder and Parkinson's disease. A deficiency in dopamine is not known to result in inflammatory related diseases.

⁷ See MPEP 2112.02.

Therefore, one skilled in the art empowered with disclosure of EP 215 would not expect that compositions employing extracts of Vitex fruits would be useful to selectively inhibit COX-2, as claimed in the method of the instant invention.

The disclosure of JP 835 does not cure this defect in the Office's obviousness rejection. JP 835 discloses that a composition **combining** Koto-sugi⁸ as the main ingredient and a portion of the rhizome of Vitex agnus-catus may be employed to treat **cancer**. Therefore, in contrast to the method of claims 1-5, 35, 37, 78-79, 81, and 85-93, nowhere does JP 835 disclose that its composition may be employed to selectively inhibit COX-2. Moreover, the skilled artisan would not assume that a composition useful for treating cancer would be similarly useful for treating COX-2 mediated diseases. In addition, as previously stated, the composition of JP 835 combines two ingredients, Koto-sugi and Vitex agnus-catus, with Koto-sugi disclosed as the "**main ingredient**." The general focus of the method of claims 1-5, 35, 37, 78-79, 81, and 85-93, on-the-other-hand, employs organic extracts of Vitex agnus-catus. A skilled artisan empowered with the disclosure of JP 835, therefore, would not expect that extracts of Vitex agnus-catus alone would either be useful to prevent cancer, as disclosed in JP 835, or for the selective inhibition of COX-2, as claimed in the instant invention.

*Nothing
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exclude
other
ingredients*

Hawley's, equally, discloses nothing pertinent to the determination of obviousness. The Office merely uses Hawley's in its obviousness rejection to establish that the use of methylene chloride as a solvent for extraction was well-known in the art. Applicants agree. But this point is not relevant to the determination of obviousness. The focus of the present invention, as defined by claims 1-5, 35, 37, 78-79, 81, and 85-93, is the **use** of an organic extract of Vitex agnus-catus to

⁸ A tree of the family Taxaceae.

selectively inhibit COX-2. The particular organic solvent employed, as stated in the specification, is not critical to the invention and is a matter of choice for the skilled artisan.⁹

Because the references relied upon by the Office, either alone or in combination, do not disclose or suggest the use of *Vitex agnus-catus* organic extracts to selectively inhibit COX-2, the Office appears to be applying "hindsight reconstruction" by using the teaching of the Applicants' patent application as a guide for searching, and analyzing the references in the right way to arrive at the claims at issue.¹⁰ Such hindsight reconstruction is clearly contrary to the law.¹¹ The *prima facie* burden of establishing that the claims would have been obvious to a skilled artisan has not been met. The Office simply does not set forth any sufficient art-based rationale as to why a person of skill in the art would have been motivated by the cited references to employ the method of the instant claims or would have had a reasonable expectation that the method would be successful.

In view of the foregoing argument, Applicants respectfully traverse this basis for rejection of claims 1-5, 35, 37, 78-79, 81, and 85-93 and request its reconsideration and withdrawal.

III. Conclusion

In light of the foregoing, Applicants request withdrawal of the claim rejections, and solicit an allowance of the claims. The Examiner is invited to contact the undersigned attorney

⁹ See page 14, at lines 3-18, of the Specification.

¹⁰ See Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193 (Fed. Cir. 1983).

¹¹ In re Dow Chemical, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988).

should any issues remain unresolved. Also, please charge our Deposit Account No. 19-1345 for any fees which may incurred.

Respectfully submitted,



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